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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,185	02/04/2004	Jude S. Sauer	LS-006CV	4686
<div>7590 Kenneth J. LuKacher, Esq. South Winton Court Suite 204 3136 Winton Road South Rochester, NY 14623</div>				
01/27/2010				
EXAMINER				
NGUYEN, VI X				
ART UNIT		PAPER NUMBER		
3731				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/772,185

**Applicant(s)**

SAUER, JUDE S.

**Examiner**

Victor X. Nguyen

**Art Unit**

3731

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 15-18 and 20-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-18 and 20-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This Office Action is in response to the amendment filed on 6/15/2009.

***Response to Amendment***

2. Accordingly, claims 1-10, 15-18, 20-31 are pending in this present application.

Applicant's arguments filed on 6/15/2009 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15-18, 20-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginn et al US 5,817,013.

Claim 1: Ginn et al disclose a proximal end having a housing 12; a shaft 16 extending from said housing to a distal end of the instrument, said shaft having at said distal end an opening (figures 1, 2) to outside of said instrument; a guide tube 20 extending from said shaft through said opening of said shaft in which said guide tube 20 comprises an outer tubular surface, two ends, and an opening extending through said guide tube between said ends of said guide tube; a path through at least said opening of said guide tube for extending a guide wire (fig. 2); and means for longitudinally cutting tissue guided along the outer tubular surface of said guide tube through said opening of said shaft, said means comprising a blade (figures 1, 2, item

18 and claim 1 of Ginn) extendable and retractable through said opening of said shaft to cut tissue when present outside of said instrument.

Claims 2-3: Ginn et al disclose the longitudinally cutting means (fig. 2) provides a cut of a predetermined depth and width; and wherein said longitudinally cutting means further comprises means at said housing coupled to said blade for remotely controlling the extending and retracting of said blade at said distal end (see col. 3, lines 56- col. 4, lines 1-21).

Claims 6-7: Ginn et al disclose when a guide wire (fig. 2) is extended along said path said distal end is located adjacent tissue along said guide wire to be cut when said blade is extended; and wherein said shaft is extendable through an endoscope (see col. 1, lines 59-63). It is noted that the limitation "said shaft is extendable through an endoscope" (an intended used limitation); a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use then it meets the claim (see MPEP 2106).

Claims 10, 15, 16: Ginn et al disclose the shaft is rigid or flexible; wherein said shaft is positionable in a tubular tissue structure through which said distal end of the instrument is guided by the guide wire along the path for extending said guide wire (fig. 2, see col. 1, lines 59-63) and said blade when extended provides the longitudinally incision along a narrowed region of the tubular structure; and wherein the guide tube 20 is non-movable with respect to the shaft.

Claims 17-18: Ginn et al disclose the path for extending the guide wire extends through said housing, said shaft 16, and said guide tube 20, and then exits said guide tube. wherein said

blade 18 is external of said guide tube and has a single longitudinally oriented sharp edge, and said means disposes said blade to extend longitudinally along the outer tubular surface of said guide tube through said opening of said shaft to enable said edge of said blade to make a longitudinal incision in tissue when present outside of said instrument (fig. 2).

Claim 25: Ginn et al disclose a shaft 16 having an end; a blade 18 at said distal end movable to extend out of said shaft to cut tissue when present outside of said instrument; and a guide member 20 which guides movement of said blade at said distal end out of said shaft; wherein said member 20 is non-movable with respect to said shaft, and said blade 18 is movable with respect to said member.

Claims 26-28: Ginn et al disclose wherein said the member 20 has an outer surface and said blade 18 is guided along said outer surface of member outside said shaft; wherein said shaft 16 has an opening to outside of said instrument (fig. 2), and said blade extends out of said shaft through said opening to cut tissue outside of said instrument which neighbors said guide member; and wherein said outer surface of said member 20 represents a tubular outer surface.

Claims 30-31: Ginn et al disclose the member has a passage for extending a guidewire through the member (fig. 2); and wherein a shaft 16 having an end; a blade 18 (Ginn, claim 1) at said end movable to extend out of said shaft to cut tissue when present outside of said instrument; and a guide member 20 which guides movement of said blade 18 at said end out of said shaft, wherein said blade is located external of said guide member, and said blade is movable with respect to said guide member 20.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5, 8-10, 20-24, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn et al in view of Spaulding US 6,036,707.

Claims 4, 8, 22, 24 and 29: Ginn et al disclose the invention substantially as claimed except for a blade shuttle attached to the blade, where the blade shuttle travels along the outer surface of the guide tube. Spaulding teaches the blade shuttle 46 attached to the blade, where the blade shuttle travels along the outer surface of the guide tube (fig. 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Gin by having the blade shuttle attached to the blade, where the blade shuttle travels along the outer surface of the guide tube as taught by Spaulding to prevent bending of the housing and to support the retention of the blade.

Claims 5, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn et al in view of Spaulding as applied to claims 1, and 8 above, and further in view of Sauer et al US 5,562,694.

Claims 5, 20: Ginn et al in view of Spaulding disclose the invention substantially as claimed except for a pivotal actuator member at the housing with one or more rods. Sauer teaches a pivotal actuator member 118 at the housing with one or more rods 252, 254. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the instrument of Gin in view of Spaulding by having a

pivotal actuator member at the housing with one or more rods as taught by Sauer to enhance the extension or retraction of the blade efficiently.

Claims 9, 10: Ginn discloses a housing 12 coupled to said shaft 16 and means for remotely controlling movement of said blade shuttle at said distal end to cut tissue; and wherein said shaft is rigid or flexible (col. 3, lines 56-col 4, lines 1-21).

Claims 21, 23: Ginn discloses a pathway through the guide tube and the shaft extends a guidewire (fig. 2), wherein the guide tube 20 is non-movable with respect to the shaft.

Claims 22, 24: Spaulding teaches said guide wire 40 is extended along said pathway to locate said distal end of the instrument adjacent the tissue to be cut by said blade, and said blade shuttle 46 is extended and retracted along said path to enable said blade to extend outside said instrument to cut said tissue (fig. 3); and wherein said blade is external of said guide tube and has a sharp edge, and said blade shuttle longitudinally travels along the outer tubular surface of said said guide tube through said opening of said shaft to enable said edge of said blade to make a longitudinal incision in tissue when present outside of said instrument (fig. 3).

### *Conclusion*

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor X Nguyen/  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
1/25/10